



PRIOR AUTHORIZATION REQUEST

GROWTH HORMONES

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for ALL PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

1	What is the patient's age? <input type="checkbox"/> Less than 12 years of age (If checked, go to 3) <input type="checkbox"/> Greater than or equal to 12 years of age (If checked, go to 2)		
2	Does the physician certify that growth hormone (somatropin) is not being used for anti-aging, longevity, cosmetic, or enhancement of athletic performance/body building purposes? [If no, no further questions.]	Yes	No

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

- 3 Which medication is being requested?
 Serostim (If checked, go to 4)

 All others (If checked, go to 5)
- 4 What is the indication or diagnosis?
 Adults with HIV infection with wasting or cachexia (If checked, go to 6)

 Other (If checked, no further questions)
- 5 Is the patient a child or an adolescent whose epiphyses are still open AND who has not reached their mid-parental height?
[NOTE: If the adolescent who was previously on growth hormone has stopped growing, the epiphyses are closed, or mid-parental height has been attained, they may be reviewed as a transition adolescent or as an adult with growth hormone deficiency OR as an adult with Prader Willi syndrome. Transition adolescents will nearly always have had a diagnosis of growth hormone deficiency. (The transition period is the time from late puberty to establishment of adult muscle and bone composition and encompasses attainment of adult height).]
 Child or adolescent (If checked, go to 7)

 Adult or transition adolescent (If checked, go to 8)
- 6 Is the request for a repeat course of Serostim? Yes No
[If yes, skip to question 9.]
[If no, skip to question 11.]
- 7 What is the indication or diagnosis?
 Growth hormone deficiency (If checked, go to 13)

 Previous radiation to the brain or tumor resection of a child (If checked, go to 14)

 Congenital hypopituitarism (If checked, go to 15)

 Panhypopituitarism [Note: GHD may occur in combination with other pituitary hormone deficiencies and is referred to as hypopituitarism, panhypopituitarism, or multiple pituitary hormone deficiency.] (If checked, go to 16)

 Hypophysectomy (surgical removal of pituitary gland) (If checked, go to 17)

 Non-growth hormone deficient short stature (idiopathic short stature) (If checked, go to 18)

 Patients with short stature associated with Turner syndrome (If checked, go to 19)

 SHOX (short stature homeobox-containing gene) deficiency (If checked, go to 20)

 Growth failure in child or adolescent with chronic kidney disease (CKD) (If checked, go to 21)

 Prader-Willi syndrome (If checked, go to 22)

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

- Children born small for gestational age (SGA) or with intrauterine growth restriction (retardation) (IUGR) including those with Silver-Russell syndrome (If checked, go to 23)
- Noonan syndrome (If checked, go to 24)
- Short bowel syndrome (If checked, go to 10)
- Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure (If checked, no further questions)
- Enhancement of athletic ability (If checked, no further questions)
- Central precocious puberty (If checked, no further questions)
- Chronic fatigue syndrome (If checked, no further questions)
- Congenital adrenal hyperplasia (CAH) (If checked, no further questions)
- Constitutional delay of growth and puberty (If checked, no further questions)
- Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation (If checked, no further questions)
- Fibromyalgia (If checked, no further questions)
- HIV-infected patients with alterations in body fat distribution (for example, increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump) (If checked, no further questions)
- Infertility (If checked, no further questions)
- Obesity (If checked, no further questions)
- Other (If checked, no further questions)

8 What is the indication or diagnosis?

- Childhood onset GH deficiency OR adult onset GH deficiency that, in the adult, results from one of the following: GH deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage (If checked, go to 25)
- Prader-Willi syndrome (If checked, go to 27)
- Short bowel syndrome in an adult (If checked, go to 10)
- Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure (If checked, no further questions)
- Aging (that is, antiaging); to improve functional status in elderly patients; and somatopause (If checked, no further questions)

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

- Enhancement of athletic ability (If checked, no further questions)
- Central precocious puberty (If checked, no further questions)
- Chronic fatigue syndrome (If checked, no further questions)
- Congenital adrenal hyperplasia (CAH) (If checked, no further questions)
- Constitutional delay of growth and puberty (If checked, no further questions)
- Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation (If checked, no further questions)
- Fibromyalgia (If checked, no further questions)
- HIV-infected patients with alterations in body fat distribution (for example, increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump) (If checked, no further questions)
- Infertility (If checked, no further questions)
- Obesity (If checked, no further questions)
- Osteoporosis (If checked, no further questions)
- Other (If checked, no further questions)

- | | | | |
|----|--|-----|----|
| 9 | Has the patient been off of Serostim for at least one month after the previous course of Serostim?
[If yes, skip to question 11.]
[If no, no further questions.] | Yes | No |
| 10 | Is the patient greater than or equal to 18 years of age? If yes, please specify age:
<hr style="width: 20%; margin-left: 0;"/> [If yes, skip to question 12.]
[If no, no further questions.] | Yes | No |
| 11 | Is the patient greater than or equal to 18 years of age? If yes, please specify age:
<hr style="width: 20%; margin-left: 0;"/> [If yes, skip to question 28.]
[If no, no further questions.] | Yes | No |
| 12 | Is the request for a second course of therapy with growth hormone (somatropin)?
[NOTE: Examples of growth hormone medications: Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zorbitive, Zomacton.]
[If yes, skip to question 29.]
[If no, skip to question 30.] | Yes | No |
| 13 | Does the patient have any of the following indications?
[NOTE: Please read the following indications below to the caller.]
<input type="checkbox"/> Previous radiation to the brain or tumor resection of a child (If checked, go to 14) | | |

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

- Congenital hypopituitarism (If checked, go to 15)
- Panhypopituitarism (If checked, go to 16)
- Hypophysectomy (surgical removal of pituitary gland) (If checked, go to 17)
- None of the above (If checked, go to 31)

14 Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
 Continuation (If checked, go to 32)

Initial (If checked, go to 33)

15 Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
 Continuation (If checked, go to 32)

Initial (If checked, go to 34)

16 Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
 Continuation (If checked, go to 32)

Initial (If checked, go to 35)

17 Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
 Continuation (If checked, go to 32)

Initial (If checked, no further questions)

18 Is this request for initial therapy or for a continuation of therapy?
[NOTE: Patients continuing growth hormone must have received at least 6 months of therapy.]
 Continuation (If checked, go to 36)

Initial (If checked, go to 37)

19 Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
 Continuation (If checked, go to 39)

Initial (If checked, no further questions)

20 Is this request for initial therapy or for a continuation of therapy?

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1-888-258-8250**

Version 02.2026

PRIOR AUTHORIZATION REQUEST

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 39)

Initial (If checked, go to 40)

21 Is this request for initial therapy or for a continuation of therapy?

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 38)

Initial (If checked, go to 41)

22 Is this request for initial therapy or for a continuation of therapy?

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 42)

Initial (If checked, go to 43)

23 Is this request for initial therapy or for a continuation of therapy?

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 32)

Initial (If checked, go to 44)

24 Is this request for initial therapy or for a continuation of therapy?

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 39)

Initial (If checked, go to 45)

25 Is documentation being provided to confirm that the patient has childhood onset GH deficiency OR adult onset GH deficiency that, in the adult, results from one of the following: GH deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage? ACTION REQUIRED: Submit supporting documentation.

Yes No

[NOTE: Medical documentation specific to your response to this question must be attached to this case or your request could be denied. Documentation may include but is not limited to, chart notes and/or laboratory data. If this documentation has been previously received upon a prior coverage review, the documentation requirement is considered to be met.]

[If no, no further questions.]

26 Has the patient been evaluated by an endocrinologist?

Yes No

[If yes, skip to question 47.]

[If no, no further questions.]

27 Is this request for initial therapy or for a continuation of therapy?

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1-888-258-8250**

Version 02.2026

PRIOR AUTHORIZATION REQUEST

[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]

Continuation (If checked, go to 48)

Initial (If checked, go to 71)

- | | | | |
|----|---|-----|----|
| 28 | Does the patient have a documented unintentional weight loss of greater than or equal to 10% from baseline, OR is the patient's weight less than 90% of the lower limit of ideal body weight, OR does the patient have a body mass index (BMI) of less than or equal to 20 kg/m ² ? ACTION REQUIRED: Submit supporting documentation.
[NOTE: The following formula can be used to calculate BMI: BMI equals body weight in kilograms divided by height meters squared (m ²) (that is, BMI = kg/m ²).]
[If yes, skip to question 49.]
[If no, no further questions.] | Yes | No |
| 29 | Has the patient responded to growth hormone (somatropin) therapy with a decrease in the requirement for specialized nutritional support according to the prescriber?
[No further questions.] | Yes | No |
| 30 | Is the patient receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet that is adjusted for individual patient requirements and preferences)?
[No further questions.] | Yes | No |
| 31 | Is this request for initial therapy or for a continuation of therapy?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
<input type="checkbox"/> Continuation (If checked, go to 32)

<input type="checkbox"/> Initial (If checked, go to 46) | | |
| 32 | What is the patient's age?
<input type="checkbox"/> Less than 12 years of age (If checked, go to 69)

<input type="checkbox"/> Greater than or equal to 12 years to less than or equal to 18 years of age (If checked, go to 59)

<input type="checkbox"/> Greater than 18 years of age (If checked, go to 57) | | |
| 33 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 51.]
[If no, no further questions.] | Yes | No |
| 34 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 52.]
[If no, no further questions.] | Yes | No |
| 35 | Does the patient have pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary "bright spot" on magnetic resonance image or computed tomography?
[If yes, skip to question 56.]
[If no, skip to question 53.] | Yes | No |

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

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|----|--|-----|----|
| 36 | <p>How long has the patient been receiving growth hormone?
 [NOTE: Patients starting growth hormone must have received at least 6 months of therapy in order to evaluate for response. Examples of growth hormone medications: Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen.]
 [NOTE: Patients starting growth hormone are evaluated for response after receiving at least 6 months of growth hormone therapy. After the first 6-month trial, patients who respond are reviewed every 12 months.]
 <input type="checkbox"/> 6 months (or less than 12 months if started with a different insurance) (If checked, go to 58)</p> <p><input type="checkbox"/> At least 10 months (If checked, go to 54)</p> | | |
| 37 | <p>Is the patient greater than or equal to 5 years of age? If yes, please specify age:</p> <p>_____</p> <p>[If yes, skip to question 60.]
 [If no, no further questions.]</p> | Yes | No |
| 38 | <p>Has the patient's height increased by greater than or equal to 2 cm/year in the most recent year AND the patient's epiphyses are still open?
 [No further questions.]</p> | Yes | No |
| 39 | <p>Has the patient's height increased by greater than or equal to 2.5 cm/year in the most recent year AND the patient's epiphyses are still open?
 [No further questions.]</p> | Yes | No |
| 40 | <p>Has short stature homeobox-containing gene (SHOX) deficiency been demonstrated by chromosome analysis?
 [If yes, skip to question 61.]
 [If no, no further questions.]</p> | Yes | No |
| 41 | <p>Does the patient have or has had chronic kidney disease (CKD) as defined by abnormal creatinine clearance?
 [If yes, skip to question 62.]
 [If no, no further questions.]</p> | Yes | No |
| 42 | <p>Has the patient's height increased by greater than or equal to 2.5 cm/year in the most recent year AND the patient's epiphyses are still open?
 [NOTE: When the epiphyses are closed and/or the height velocity is less than 2.5 cm/year, the patient can be reviewed for continuation of therapy as an adult with Prader-Willi syndrome.]
 [No further questions.]</p> | Yes | No |
| 43 | <p>Has the patient been evaluated by an endocrinologist?
 [No further questions.]</p> | Yes | No |
| 44 | <p>Is the patient greater than or equal to 2 years of age? If yes, please specify age:</p> <p>_____</p> <p>[If yes, skip to question 63.]
 [If no, no further questions.]</p> | Yes | No |
| 45 | <p>Has the patient been evaluated by an endocrinologist?
 [If yes, skip to question 64.]
 [If no, no further questions.]</p> | Yes | No |

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

- | | | | |
|----|---|-----|----|
| 46 | <p>Has the patient had TWO growth hormone (GH) stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND both tests show an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory?</p> <p>[NOTE: Some children will achieve stimulated growth hormone concentrations in the normal range as determined by the testing laboratory and could be reviewed for authorization under non-growth hormone deficient short stature (idiopathic short stature).]
 [If yes, skip to question 71.]
 [If no, skip to question 50.]</p> | Yes | No |
| 47 | <p>Is the patient an adult or transition adolescent who has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects?</p> <p>[If yes, skip to question 75.]
 [If no, skip to question 76.]</p> | Yes | No |
| 48 | <p>Has the patient been evaluated by an endocrinologist or in consultation with an endocrinologist?</p> <p>[No further questions.]</p> | Yes | No |
| 49 | <p>Has wasting or cachexia that is due to malabsorption, poor diet, opportunistic infection, depression, and other causes been addressed prior to starting Serostim?</p> <p>[If yes, skip to question 65.]
 [If no, no further questions.]</p> | Yes | No |
| 50 | <p>Has the patient had one growth hormone (GH) stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory?</p> <p>[NOTE: Some children will achieve stimulated growth hormone concentrations in the normal range as determined by the testing laboratory and could be reviewed for authorization under non-growth hormone deficient short stature (idiopathic short stature).]
 [If yes, skip to question 66.]
 [If no, no further questions.]</p> | Yes | No |
| 51 | <p>Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory; OR the patient has a deficiency in at least one other pituitary hormone (that is, adrenocorticotrophic hormone (ACTH), thyroid-stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), or prolactin)?</p> <p>[No further questions.]</p> | Yes | No |
| 52 | <p>Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory; OR the patient has a deficiency in at least one other pituitary hormone (that is, adrenocorticotrophic hormone (ACTH), thyroid-stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency),</p> | Yes | No |

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

or prolactin) and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk?
 [No further questions.]

- | | | | |
|----|---|-----|----|
| 53 | Does the patient have three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin?
[If yes, skip to question 56.]
[If no, skip to question 55.] | Yes | No |
| 54 | What is the patient's age?
<input type="checkbox"/> Greater than or equal to 5 years to less than 12 years of age (If checked, go to 69)

<input type="checkbox"/> Greater than or equal to 12 years to less than or equal to 18 years of age (If checked, go to 59)

<input type="checkbox"/> Greater than 18 years of age (If checked, go to 57)

<input type="checkbox"/> Less than 5 years of age (If checked, no further questions) | | |
| 55 | Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory?
[If yes, skip to question 56.]
[If no, no further questions.] | Yes | No |
| 56 | Has the patient been evaluated by an endocrinologist?
[No further questions.] | Yes | No |
| 57 | Has the patient attained his/her mid-parental height?
[NOTE: Mid-parental height is the father's height plus the mother's height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female.]
[If yes, skip to question 59.]
[If no, no further questions.] | Yes | No |
| 58 | What is the patient's age?
<input type="checkbox"/> 5 years of age or older (If checked, go to 68)

<input type="checkbox"/> Less than 5 years of age (If checked, no further questions) | | |
| 59 | Are the patient's epiphyses still open?
[If yes, skip to question 69.]
[If no, no further questions.] | Yes | No |
| 60 | Does the patient have constitutional delay of growth and puberty (CDGP)?
[If yes, no further questions.]
[If no, skip to question 70.] | Yes | No |
| 61 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 72.]
[If no, no further questions.] | Yes | No |

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

62	Has the patient been evaluated by an endocrinologist or a nephrologist? [No further questions.]	Yes	No
63	Has the patient been evaluated by an endocrinologist? [If yes, skip to question 73.] [If no, no further questions.]	Yes	No
64	At baseline, is the patient's height less than the 5th percentile using a growth chart for children without Noonan syndrome? [No further questions.]	Yes	No
65	Has the patient been on antiretroviral therapy or highly active antiretroviral treatment (HAART) for greater than or equal to 30 days prior to beginning therapy with Serostim AND will continue antiretroviral therapy throughout the course of treatment with Serostim? [If yes, skip to question 67.] [If no, no further questions.]	Yes	No
66	Does the patient have at least one risk factor for growth hormone deficiency? [NOTE: For example, the height for age curve has deviated downward across two major height percentiles (for example, from above the 25th percentile to below the 10th percentile); the child's growth rate is less than the expected normal growth rate based on age and gender; low IGF-1 and/or IGFBP-3 levels; the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician; the child's growth velocity is less than the 10th percentile for age and gender (height velocity percentile is NOT the same as height-for-age percentile); the patient is status post craniopharyngioma resection; the patient has optic nerve hypoplasia; the patient has a growth hormone gene deletion.] [If yes, skip to question 71.] [If no, no further questions.]	Yes	No
67	Is Serostim being used solely for the treatment of alterations in body fat distribution such as increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump? [No further questions.]	Yes	No
68	After the initial 6 months of therapy, did the patient have an adequate clinical response defined as an annualized growth rate that doubled in comparison to the previous year [NOTE: For example, if the growth velocity was 3 cm/year for the year prior to treatment, then the growth velocity must be at least 3 cm in 6 months (baseline velocity was 1.5 cm/6 months).]? [NOTE: Another example would be if the growth velocity was 2 cm/year for the year prior to treatment, then after 6 months of somatropin therapy, the growth velocity must be at least 2 cm in 6 months (1 cm/6 months baseline).] [No further questions.]	Yes	No
69	Has the patient's height increased by greater than or equal to 4 cm/year in the most recent year? [No further questions.]	Yes	No
70	Are the patient's epiphyses still open? [If yes, skip to question 83.] [If no, no further questions.]	Yes	No

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

71	Has the patient been evaluated by an endocrinologist? [No further questions.]	Yes	No
72	Are the patient's epiphyses still open? [If yes, skip to question 87.] [If no, no further questions.]	Yes	No
73	Was the patient's birth weight and/or birth length greater than 2 standard deviations (SD) below the mean for gestational age and gender AND the patient did not have sufficient catch-up growth before age 2 to 4 years? [If no, no further questions.]	Yes	No
74	At baseline, is the patient's height less than the 5th percentile for age and gender? [No further questions.]	Yes	No
75	Is documentation being provided to confirm that the adult or transition adolescent has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects? ACTION REQUIRED: Submit supporting documentation [No further questions.]	Yes	No
76	Does the adult or transition adolescent have three or more of the following pituitary hormone deficiencies: adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin? [If no, skip to question 81.]	Yes	No
77	Is documentation being provided to confirm that the adult or transition adolescent has three or more of the following pituitary hormone deficiencies: adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
78	Is the age and gender adjusted serum IGF-1 below the lower limits of the normal reference range for the reporting laboratory? [If no, skip to question 81.]	Yes	No
79	Is documentation being provided to confirm that the patient has an age and gender adjusted serum IGF-1 below the lower limits of the normal reference range for the reporting laboratory? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
80	Have other causes of low serum IGF-1 been excluded (for example, malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy)? [If yes, no further questions.]	Yes	No
81	Is the patient an adult OR a transition adolescent with childhood onset growth hormone deficiency who is transitioning from growth hormone therapy in childhood to adulthood (The transition period is the time from late puberty to establishment of adult muscle and bone composition, and encompasses attainment of adult height)?		

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

Transition adolescent (If checked, go to 82)

Adult (If checked, go to 89)

- 82 As a transition adolescent, has the patient been off somatropin therapy (growth hormone) for at least one month before being retested with a growth hormone stimulation test? Yes No
[If yes, skip to question 88.]
[If no, no further questions.]
- 83 At baseline, is the patient's height less than the 1.2 percentile (standard deviation score [SDS] less than -2.25) for age and gender? Yes No
[If no, no further questions.]
- 84 Without growth hormone therapy, is the patient's predicted adult height less than 160 cm (63 inches) if male or less than 150 cm (59 inches) if female? Yes No
[If no, no further questions.]
- 85 What is the patient's pretreatment growth (height) velocity [growth rate] measured in cm/year?
 4cm/year or greater (If checked, go to 86)
 Less than 4cm/year (If checked, no further questions)
- 86 Based on age, gender, and at least 6 months of growth data, in what percentile is the patient's pretreatment growth (height) velocity [growth rate]?
[NOTE: height velocity percentile is NOT the same as height for age percentile.]
 At or above the 10th percentile (If checked, no further questions)
 Below the 10th percentile (If checked, no further questions)
- 87 At baseline, is the patient's height less than the 3rd percentile for age and gender? Yes No
[No further questions.]
- 88 Is documentation being provided to confirm that as a transition adolescent, the patient has been off somatropin therapy (growth hormone) for at least one month before being retested with a growth hormone stimulation test? ACTION REQUIRED: Submit supporting documentation. Yes No
[If yes, skip to question 106.]
[If no, no further questions.]
- 89 Has the adult patient had a negative response to one of the following standard growth hormone stimulation tests?
 Insulin tolerance test (If checked, go to 90)
 Glucagon stimulation test (If checked, go to 92)
 Macrilen (macimorelin) test (If checked, go to 102)
 Arginine alone test (If checked, go to 105)
 No (If checked, no further questions)

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

90	<p>Has the adult patient had a peak response of 5 micrograms per liter or less with the insulin tolerance test? [If no, no further questions.]</p>	Yes	No
91	<p>Is documentation being provided to confirm that the adult patient has had an insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with a peak response of 5.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]</p>	Yes	No
92	<p>What is the adult patient's body mass index (BMI)? <input type="checkbox"/> Greater than 30 kg/m² (If checked, go to 93) <input type="checkbox"/> Greater than or equal to 25 kg/m² and less than or equal to 30 kg/m² (If checked, go to 95) <input type="checkbox"/> Less than 25 kg/m² (If checked, go to 94)</p>		
93	<p>Has the adult patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 100.] [If no, no further questions.]</p>	Yes	No
94	<p>Has the adult patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 101.] [If no, no further questions.]</p>	Yes	No
95	<p>According to the prescriber, does the patient have a high pretest probability of GH deficiency or a low pretest probability of GH deficiency? <input type="checkbox"/> High pretest probability of GH deficiency (If checked, go to 96) <input type="checkbox"/> Low pretest probability of GH deficiency (If checked, go to 97)</p>		
96	<p>Has the adult patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 98.] [If no, no further questions.]</p>	Yes	No
97	<p>Has the adult patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 99.] [If no, no further questions.]</p>	Yes	No
98	<p>Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than or equal to 25 kg/m² and less than or equal to 30 kg/m² with, according to the prescriber, a high pretest probability of GH deficiency had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]</p>	Yes	No

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

99	Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than or equal to 25 kg/m ² and less than or equal to 30 kg/m ² , with a low pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
100	Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than 30 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
101	Is documentation being provided to confirm that the adult patient with body mass index (BMI) less than 25 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
102	What is the adult patient's body mass index (BMI)? <input type="checkbox"/> Greater than 40 kg/m ² (If checked, no further questions) <input type="checkbox"/> Less than or equal to 40 kg/m ² (If checked, go to 103)		
103	Has the adult patient had a Macrilen (macimorelin) test with a peak response of less than 2.8 nanograms/milliliter (2.8 micrograms/liter)? [If no, no further questions.]	Yes	No
104	Is documentation being provided to confirm that the adult patient with body mass index (BMI) less than or equal to 40 kg/m ² had a Macrilen (macimorelin) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with a peak response of less than 2.8 micrograms per liter? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
105	Has the adult patient had a peak response of 0.4 micrograms/liter or less with the arginine alone test? [No further questions.]	Yes	No
106	Has the transition adolescent patient had a negative response to one of the following standard growth hormone stimulation tests? <input type="checkbox"/> Insulin tolerance test (If checked, go to 107) <input type="checkbox"/> Glucagon stimulation test (If checked, go to 109) <input type="checkbox"/> Arginine alone test (If checked, go to 119) <input type="checkbox"/> Macrilen (macimorelin) test (If checked, go to 123) <input type="checkbox"/> No (If checked, no further questions)		

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

107	<p>Has the transition adolescent patient had a peak response of 5 micrograms per liter or less with the insulin tolerance test? [If no, no further questions.]</p>	Yes	No
108	<p>Is documentation being provided to confirm that the transition adolescent patient had an insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with a peak response of 5.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]</p>	Yes	No
109	<p>What is the transition adolescent patient's body mass index (BMI)? <input type="checkbox"/> Less than 25 kg/m² (If checked, go to 111) <input type="checkbox"/> Greater than or equal to 25 kg/m² and less than or equal to 30 kg/m² (If checked, go to 112) <input type="checkbox"/> Greater than 30 kg/m² (If checked, go to 110)</p>		
110	<p>Has the transition adolescent patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 118.] [If no, no further questions.]</p>	Yes	No
111	<p>Has the transition adolescent patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 117.]</p>	Yes	No
112	<p>According to the prescriber, does the patient have a high pretest probability of GH deficiency or a low pretest probability of GH deficiency? <input type="checkbox"/> High pretest probability of GH deficiency (If checked, go to 114) <input type="checkbox"/> Low pretest probability of GH deficiency (If checked, go to 113)</p>		
113	<p>Has the transition adolescent patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 115.] [If no, no further questions.]</p>	Yes	No
114	<p>Has the transition adolescent patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test? [If yes, skip to question 116.] [If no, no further questions.]</p>	Yes	No
115	<p>Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) greater than or equal to 25 kg/m² and less than or equal to 30 kg/m², with low pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]</p>	Yes	No

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Version 02.2026

PRIOR AUTHORIZATION REQUEST

116	Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) greater than or equal to 25 kg/m ² and less than or equal to 30 kg/m ² , with a high pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
117	Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) less than 25 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
118	Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) greater than 30 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
119	Are both the insulin tolerance test and the glucagon stimulation test contraindicated? [If no, no further questions.]	Yes	No
120	Is documentation being provided to confirm that the transition adolescent patient has contraindications to both the insulin tolerance test and the glucagon stimulation test? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
121	Has the transition adolescent patient had a peak response of 0.4 micrograms/liter or less with the arginine alone test? [If no, no further questions.]	Yes	No
122	Is documentation being provided to confirm that the transition adolescent patient had an arginine alone test obtaining at least 3 growth hormone levels in at least 120 minute timeframe (not including a level at timeframe zero) with a peak response of 0.4 micrograms/liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
123	Has the transition adolescent patient had a Macrilen (macimorelin) test with a peak response of less than 2.8 nanograms/milliliter (2.8 micrograms/liter)? ACTION REQUIRED: Submit supporting documentation.	Yes	No

Please document the diagnoses, symptoms, and/or any other information important to this review:

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Version 02.2026



PRIOR AUTHORIZATION REQUEST

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

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